# Minimal unilateral peak nasal inspiratory flow correlates with patient reported nasal obstruction\*

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# Abstract

**Background**: Nasal septoplasty is a common surgical procedure, but a significant number of patients report equal, or some even worsened, symptom load postoperatively. Rhinologists struggle to find objective tests that adequately reflects disease burden. This study aimed to evaluate the correlation between the PNIF measurement of the most obstructed side with patient reported outcomes.

**Methods**: Bilateral and unilateral PNIF measurements were performed before and after topical decongestion in 528 patients scheduled for surgery due to nasal obstruction. Subjective outcomes were measured using Nasal Obstruction VAS and SNOT-22 with subdomains. Correlations between subjective and objective measurements were calculated and further explored using multivariate regression analyses.

**Results**: Significant negative correlations between PNIF and patient reported outcomes were found. Both bilateral and minimal unilateral PNIF correlations with NO-VAS were equal and stronger than correlations with SNOT-22 including subdomains concerning problems with nasal obstruction. Minimal unilateral PNIF did not show statistically significant gender difference. Topical decongestion decreased statistical correlations.

**Conclusions**: The minimal unilateral PNIF shows a statistically significant but weak negative correlation with preoperative patient reported nasal obstruction, and values do not differ between genders. Clinical evaluation of patients presenting complaints of nasal obstruction could be supported by minimal unilateral PNIF.

Key words: nasal obstruction, nasal surgical procedures, visual analog scale, diagnostic techniques, respiratory system, patient reported outcome measures

# Introduction

About 0,1% of the population in western countries undergo nasal septoplasties annually, based on 260000 reported surgeries in the US<sup>(1)</sup>, 95000 in Germany<sup>(2)</sup> and 4300 in Norway<sup>(3)</sup>. Septoplasty is generally considered a safe procedure. Recent large scale register-based studies report complication rates of 3.4%<sup>(4)</sup>, but that one out of four patients report symptom load equal (21%) or worsened (3%) after septoplasty<sup>(5)</sup>. This shows that every year, many patients worldwide undergo surgery without relief of their presenting complaints. Practicing medicine by the maxim "Primum non nocere" or "Firstly, to do no harm", it is every surgeon's responsibility to reduce the number of unnecessary operations, and hence complications. Outcome is influenced by different factors, but correct diagnosis and proper patient selection is essential.

No single or set of signs and symptoms are universally accepted to qualify patients for nasal septoplasty. Decisions are rather based on subjective patient reports and surgeon's preference and clinical experience.

Peak Nasal Inspiratory Flow (PNIF) is a cheap, quick and simple examination of nasal inspiratory airflow. The aim of this study was to evaluate how well objective results from unilateral and bilateral PNIF measurements correlated with subjective complaints in patients referred to a rhinology hospital clinic due to nasal obstruction. Our primary objective was to study whether unilateral PNIF measurements correlated better than bilateral measurements to subjective patient reported outcome measures (PROMs). We specifically wanted to examine Nasal Obstruction Visual Analogue Scale (NO-VAS) and the SinoNasal Outcome Test 22 (SNOT-22). Secondarily we wanted to identify significant confounding factors when comparing subjective and objective measurements, and analyse SNOT-22 vs. NO-VAS correlation in a population with nasal obstruction. We hypothesised that unilateral PNIF can supplement the surgeon's examination in pre- and postoperative diagnostics to improve patient selection for surgery and reduce unnecessary harm.

### **Materials and methods**

#### **Study design**

A prospective observational study of all patients scheduled for surgical treatment due to subjective nasal obstruction between 1 September 2014 and 9 June 2016 was performed at Akershus University Hospital, Norway. Both ENT registrars and consultant doctors enrolled and operated patients. Eligibility criteria, in addition to being scheduled for surgery, were informed consent, age 18 years or above, non-pregnant, no septal perforation or previous nasal surgery, mental and physical ability to participate in objective measurements and independently complete written questionnaires in Norwegian.

### Patients

A total of 558 patients enlisted for rhinosurgery were recruited after informed consent. Study participation did not influence choice of treatment, and vice versa. 30 patients were excluded from the study because of failure to perform subjective or objective measurements satisfactorily. Population characteristics and scheduled surgical procedures for the 528 included patients are presented in Table 1. Information on height, weight, smoking, asthma and allergy are patient-reported. Patients with allergies were included and tested throughout the year without regard to seasonal complaints. Questionnaires with subjective data were answered on paper on the same day that objective data were collected by trained study nurses.

#### **Peak Nasal Inspiratory Flow**

Youlten peak flow meters (Clement Clarke International) fitted with a transparent mask were used. The instrument measures values of flow from 30 to 370 L/min, with 5 L/min increments. Flow values <30 were recorded as 0 L/min. PNIF measurements were standardized by having the patient seated on a chair in a Table 1. Demographic and anthropometric data and scheduled surgeries. Values expressed as mean.

Total	528
Female (%)	181 (34.3%)
Age (SD)	37.0 (13.0)
Height, cm (SD)	176 (9.27)
Weight, kg (SD)	79.6 (16.8)
BMI, kg/m <sup>2</sup> (SD)	25.6 (4.50)
Smoking (%)	78 (14.8%)
Asthma (%)	96 (18.5%) *
Allergy (%)	250 (48.3%) **
Septoplasty	38 (7.2%)
Septoplasty with turbinate surgery	231 (43.8%)
Turbinate surgery	146 (27.7%)
FESS and Septoplasty	58 (11.0%)
Rhinoseptoplasty	55 (10.4 %)
*: N = 519, **: N= 518	

quiet, temperature-controlled room<sup>(6)</sup>. They were instructed to exhale before fitting the mask snugly without compressing or pulling on the cartilaginous part of the nose, then draw their breath through the nose with as much force as possible. A nurse controlled the patient performance, technique and position of the transparent mask, making sure no leakage or deformation of the nose occurred. This procedure was repeated until two consecutive measurements differed  $\leq 10\%$  and the technique and performance were considered satisfactory. The highest value was recorded. Unilateral values were obtained by closing one nostril at a time with medical grade tape, making sure not to deform the nasal alae. Repeat measurements were recorded 15 minutes after decongestion with topical oxymetazoline 0.5 mg/ml. Unilateral PNIF values were grouped according to side of lowest and highest flow as Minimal (MinPNIF) and Maximal unilateral Peak Nasal Inspiratory Flow (MaxPNIF), respectively.

# Patient Reported Outcome Measures (PROMs) SinoNasal Outcome Test 22 (SNOT-22)

The SNOT-22 is a commonly applied PROM for patients with sinonasal complaints, and has been extensively investigated and used in studying patients with chronic rhinosinusitis<sup>(7)</sup>, septorhinoplasty<sup>(8)</sup> and nasal septoplasty with and without concomitant turbinate surgery<sup>(9)</sup>. We used the Norwegian translation where the patients are asked to evaluate their problems as they had been the past two weeks. All 22 items are reported on a 6-point Likert scale from 0 to 5, 0 equalling "No problem" to 5 "Problem as bad as it can be". For data analysis the nasal obstruction-specific item SNOT-4 (the fourth question: "Nasal obstruction"), the

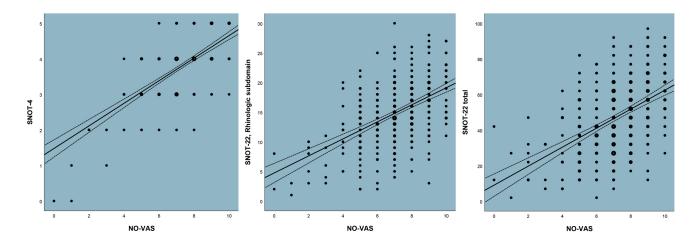


Figure 1. Nasal Obstruction Visual Analogue Scale (NO-VAS) score by SinoNasal Outcome Test 22 (SNOT-22) nasal obstruction-specific question (SNOT-4), rhinologic subdomain and total test score.

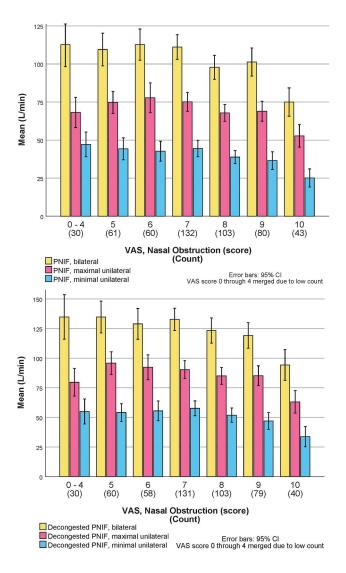


Figure 2. Mean Peak Nasal Inspiratory Flow (PNIF) before and after decongestion by Nasal Obstruction Visual Analogue Scale (NO-VAS) score.

rhinologic subdomain SNOT-Rhino (including the six questions measuring rhinologic symptoms: "need to blow nose", "sneezing", "runny nose", "nasal obstruction", "loss of smell or taste" and "thick nasal discharge")<sup>(10)</sup> and SNOT-22 (the total sum of all 22 items) were used.

Nasal Obstruction Visual analogue scale (NO-VAS) The patients were asked to evaluate their experience of nasal obstruction during the past two weeks on a 100 mm visual analogue scale (VAS), results are measured and reported approximated to the nearest full centimetre from 0 to 10. The scale ranged from 0 "completely open" to 10 "completely obstructed".

#### **Missing data**

All subjective outcome items had <4% missing data, while missing PNIF measurements were <2% each. When constructing the total SNOT-22 sum, cases with one or more missing items added up to 17.5%. SNOT-22 has been subdivided into subdomains(10). We chose to impute missing SNOT-22 items with the same patient's mean of valid items from same SNOT-22 subdomain. Because the variability of means was lower within subdomains we considered this method improved previous practise of SNOT-22 imputation with the mean of all valid items<sup>(7)</sup>. If  $\geq$ 50% of the subdomain items were missing, no imputation was done. This method of missing data imputation is common where individual items are missing in PROMs and has been shown to be the best method of data imputation in multi-item scales<sup>(11)</sup>.

#### **Statistical analysis**

Statistical analyses were performed with IBM SPSS Statistics 25, 64-bit edition for Windows. Nominal data were presented as frequencies and percentages, while ordinal and nominal data were presented as means ± standard deviations. Comparisons between groups were performed with parametric independent

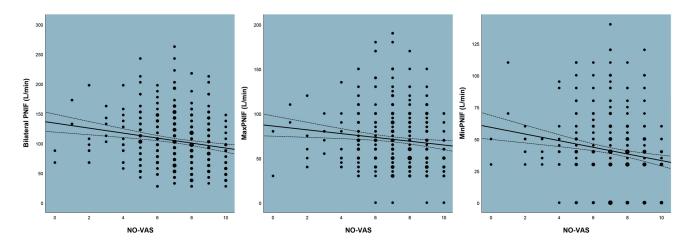


Figure 3. Bilateral, maximal unilateral and minimal unilateral Peak Nasal Inspiratory Flow (PNIF) by Nasal Obstruction Visual Analogue Scale (NO-VAS) score.

t-test. Correlations were done using Pearson correlation and are presented as Pearson correlation coefficients. Further exploration of NO-VAS correlation with bilateral and minimal PNIF were performed using multivariate linear regression analyses adjusting for the possible confounders age, gender, height, weight, asthma, allergy and smoking. Confounders were excluded using the backward elimination method with removal criteria of p > 0.1. Two-sided P values of <0.05 were considered significant.

### Approvals

The study attained approval from the regional ethics committee (ref. 2018/1020) and hospital patients' rights ombudsman (ref. 14-067).

## Results

#### **Patient demographics**

As shown in Table 1, twice as many men as women were included. The majority of patients scheduled for septoplasty were also planned for concomitant turbinate surgery. Table 2 display differences in means between demographic subgroups. Male patients had higher flows both for bilateral PNIF and MaxPNIF. There was also a significant gender difference in decongested MinPNIF, but not for baseline MinPNIF. Patients with BMI categories overweight and obese (>25 kg/m<sup>2</sup>) had significantly higher baseline flows than patients in normal or underweight categories. This difference was not reproduced after decongestion. Overweight and obese patients also reported significantly higher NO-VAS and total SNOT-22 scores, but not isolated SNOT-4 or SNOT-Rhino scores. Patients reporting allergy present significantly higher NO-VAS and decongested MinPNIF.

### **Correlation of VAS and SNOT**

PROM intercorrelations were moderate to strong, positive and highly statistically significant. Pearson correlation coefficients

were VAS – SNOT-4 (r=.646), VAS – SNOT-Rhino (r=.500) and VAS – SNOT-22 (r=.483), all p <.001. The data and regression lines with 95% confidence intervals are shown in Figure 1.

## **Correlation of PNIFs and PROMs**

Bilateral PNIF, MinPNIF and MaxPNIF bivariate correlations with NO-VAS, SNOT-4, SNOT-Rhino and SNOT-22 are presented in Table 3 both for baseline and decongested values. Correlations were negative and highly statistically significant, but Pearson r values were weak. Generally, decongested PNIF values showed similar correlations. NO-VAS provided higher correlation coefficients with both bilateral and MinPNIF than the three SNOT measures, and similar results were reproduced with decongested measurements. Figure 2 demonstrates the relationship between mean baseline and decongested bilateral PNIF, MaxPNIF and MinPNIF and NO-VAS score, while Figure 3 display bilateral PNIF, MaxPNIF and MinPNIF by NO-VAS showing regression lines with 95% confidence intervals.

#### **NO-VAS multivariate regression analysis**

Multivariate regression analysis was used to test whether bilateral or minimal unilateral PNIF and various sociodemographic and anthropometric factors significantly predicted NO-VAS. The associations between NO-VAS and both bilateral and MinPNIF found using multivariate regression analyses were weak but highly statistically significant.

Analysing bilateral PNIF proved a significant regression model where six factors explained 6.4% of the variance (R2=.064, p<.000). It was found that increasing bilateral PNIF (L/min) ( $\beta$ =-.008, p<.000), age (years) ( $\beta$ =-.013, p=.062) and height (cm) ( $\beta$ =-.020, p=.061) predicted lower NO-VAS scores, while higher weight (kg) ( $\beta$ =.017, p=.007) and allergy ( $\beta$ =.384, p=.014) predicted higher NO-VAS. Gender, asthma and smoking did not

MaxPNIF, decongested L/min 68.5 95.3 <.001 87.8	MinPNIF, decongested L/min 46.3 55.0 .001 52.1	PNIF Bilateral, decongested L/min 105.6 134.6 <.001 51.9	MaxPNIF L/min 58.5 76.5 <.001 69.0	MinPNIF L/min 38.1 41.3 .156 38.4	PNIF Bilateral L/min 89.8 110.3 <.001 100.1	SNOT-22 total 0-110 50.7 45.1 .003 46.7	SNOT-Rhino 0-30 15.6 14.6 .052 15.2	SNOT-4 0-5 3.75 3.74 .903 3.82	NO-VAS 0-10 7.16 7.17 .931 7.27	Female Male Sig. ≤35	Gender Ag
84.8 .3	52.0 .9	53.0 .2	71.9 .3	42.2 .1	106.5 .0	47.37	14.7 .2	3.65 .0	7.06 .1	>35 S	Age (years)
.391 8	.977 5	.403 12	.300 6	.100 3	.084 9	.736 4.	.267 1.	.033 3.	.179 7.	Sig. ≤	
83.2	51.0	121.1 1	67.3	37.5	98.6 1	45.1	14.7	3.71	7.00	≤25	BMI
89.0	53.0	128.0	73.2	42.7	107.4	48.7	15.1	3.77	7.31	>25	BMI (kg/m²)
.090	.483	.134	.033	.026	.018	.042	.358	.437	.048	Sig.	('
85.8	52.6	125.0	70.3	40.6	103.3	46.3	14.7	3.72	7.13	No	S
89.2	49.0	123.7	70.9	38.1	103.1	50.8	16.3	3.84	7.38	Yes	Smoking
.479	.369	.847	.886	.439	.968	.078	.015	.284	.258	Sig.	
85.1	51.0	124.4	69.7	39.0	102.7	45.8	14.7	3.72	7.15	No	
90.2	54.7	126.6	72.0	43.9	104.8	52.9	16.5	3.85	7.34	Yes	Asthma
.253	.313	.706	.525	.101	.651	.002	.003	.205	.342	Sig.	
85.1	48.9	122.5	69.0	37.9	101.2	46.6	14.7	3.70	7.00	No	
87.6	55.1	126.3	71.7	42.4	104.7	47.6	15.4	3.79	7.35	Yes	Allergy
.470	.030	.416	.324	.060	.356	.573	.155	.256	.026	Sig.	

Table 2. Subjective and objective measure comparisons between demographic subgroups. Values are expressed as mean.

contribute significantly to the model and were excluded. MinPNIF showed a significant regression model where five factors explained 6.3% of the variance (R2=.063, p<.000). It was found that MinPNIF (L/min) ( $\beta$ =-.012, p<.000), age (years) ( $\beta$ =-.012, p=.062) and height (cm) ( $\beta$ =-.027, p=.015) predicted lower NO-VAS scores, while weight (kg) ( $\beta$ =.018, p=.005) and allergy ( $\beta$ =.384, p=.015) predicted higher NO-VAS. As with Bilateral PNIF, gender, asthma and smoking were excluded as they did not contribute significantly to the model.

#### Data transformation

Analysis of mathematically transformed PNIF values using both common logarithmic and square root transformations did not yield improved correlations compared to using original values.

## Discussion

Peak Nasal Inspiratory Flow is an excellent candidate measure for the evaluation of nasal airflow in all clinical and home settings due to its low price, quick analysis and ease of use. However, PNIF represent a maximal air flow that is not often encountered in daily life. Normative PNIF values have been published for different populations by, among others, Ottaviano and Klossek with their respective groups(12-14). Available data show considerable differences in mean PNIF measurements between presumably comparable groups. Whether this results from differences between the populations or measurement techniques remain uncertain. PNIF has been shown to be highly reproducible<sup>(15)</sup> and well suited to identify patients with clinically relevant nasal stenosis<sup>(16, 17)</sup>. It is positively correlated with pulmonary ventilatory capacity measured by peak expiratory flow (PEF)<sup>(18)</sup>, male sex, height and inversely with age<sup>(12)</sup> and asthma status<sup>(19)</sup>. PNIF correlates and compares to the gold standard of nasal airflow measurement, rhinomanometry<sup>(20-22)</sup>, and acoustic rhinometry<sup>(23)</sup>. A recent publication by Døsen et al. in a similar preoperative cohort presents a negative correlation between NO-VAS and unilateral PNIF<sup>(24)</sup>. In a recent edition of this journal Hoven et al. published their findings of similar correlations in a large cohort of patients with sleep disordered breathing<sup>(25)</sup>.

Our material has considerable heterogeneity considering patient population, pathology, surgeon experience and planned surgical intervention. This is a strength when considering PNIF as a screening or decision helping tool when evaluating patients referred due to subjective nasal obstruction. NO-VAS is commonly used in the assessment of nasal obstruction and has been shown to correlate strongly with rhinomanometry nasal airflow resistance in patients with allergic rhinitis<sup>(26)</sup>. A recent study shows moderate negative correlation between unilateral NO-VAS and same side unilateral PNIF in patients undergoing septorhinoplasty<sup>(27)</sup>. Meanwhile, the extensively used and researched SNOT-22 questionnaire evaluates several aspects and dimensions of sinonasal function. Consequently, making use of single questions and subdomains from the questionnaire proves helpful. The Nasal Obstruction and Septoplasty Effectiveness (NOSE) scale is commonly used and referenced in English literature when nasal obstruction is studied. In the Norwegian

		PNIF Bilateral	MinPNIF	MaxPNIF	PNIF Bilateral, decongested	MinPNIF, decongested	MaxPNIF, decongested
NO-VAS	Pearson r	177	176	120	152	129	107
	Sig.	<.001	<.001	0.007	.001	.004	.016
SNOT-4	Pearson r	153	143	-0.082	087	110	049
	Sig.	<.001	0.001	0.062	.048	.013	.272
SNOT-Rhino	Pearson r	155	126	123	160	155	118
	Sig.	<.001	0.004	0.005	<.001	<.001	.007
SNOT-22	Pearson r	171	-0.074	159	189	123	166
	Sig.	<.001	0.091	<.001	<.001	.005	<.001

Table 3. Correlation of PNIFs and PROMs.

language there is no clear distinction between the sensation terms "obstruction", "blockage", "stuffiness" and "congestion" of the nasal airway. Hence, we have chosen not to translate and apply the NOSE scale in this study.

PROM intercorrelations in our study are generally strong. One could suspect even stronger correlations, in particular when comparing the single question items NO-VAS and SNOT-4 that essentially measures the same sensation of nasal obstruction on different scales. Our data show a correlation of r=.646 between the two. Many factors influence how patients respond to PROM questionnaires. Our cohort might be affected by many patients responding to the questionnaires in Norwegian as a foreign language as Akershus University Hospital serves the Norwegian region with the largest non-western immigrant population<sup>(28)</sup>.

In our selected population, both minimal unilateral and bilateral PNIF values are considerably below normative ranges. We observe lower flow values and higher patient reported obstruction when comparing to the similar cohort presented by Døsen et al.<sup>(24)</sup>. Our material showed mean bilateral PNIF (Q :89.8, 0<sup>o</sup> :110.3) versus (Q :120.1,0<sup>o</sup> :131.1) and NO-VAS (Q :7.16, 0<sup>o</sup> :7.17) versus (Q :6.08,0<sup>o</sup> :6.31). This could be due to differences in underlying pathologies, ethnical distribution and cultural differences or technical and methodological variances.

NO-VAS correlates better than SNOT-4, SNOT-Rhino and SNOT-22 with PNIF measurements and seems to be preferable in evaluating nasal obstruction. These PNIF versus PROM correlations confirm previously published results in populations with nasal pathology<sup>(17, 24, 25)</sup>. Rhinomanometry and acoustic rhinometry have shown comparable correlations with NO-VAS, but with considerable heterogeneity of patient cohorts and relatively large discrepancy in correlation coefficients<sup>(13, 17, 29-33)</sup>. Hence, conclusions on the superiority or inferiority of one objective measure over the other should be drawn with caution. MinPNIF provides results similar to bilateral PNIF when correlated with NO-VAS, also when corrected for anthropometric properties using multivariate regression analyses. This correspond to results presented by Thorstensen et al. using bilateral measurements<sup>(19)</sup>. MaxPNIF generally had weaker correlations and significance levels. It is known from the extensive work of Ottaviano et al.<sup>(12, 14)</sup> that both bilateral and unilateral PNIF values show considerable gender differences in healthy adult populations. In our material MinPNIF did not show statistically significant gender difference, (p=.156, ♀ :38.1, ♂ :41.3), as opposed to bilateral measurements (p<.000, ♀ :89.8, ♂ :110.3). Repeat measurement after topical decongestion did not improve correlations. Eliminating this step from routine PNIF measurements in clinical practise could reduce time spent per patient. Similarly, logarithmic or square root transformations of PNIF values did not change correlations, and they did not reveal any non-linear statistical relationships.

The main strength of our study in addition to a large material is heterogeneity of the cohort and participating hospital staff, replicating everyday clinical practise. It also presents a large material including unilateral and decongested values for all participants. We acknowledge that stringent screening of patients, including linguistic competences, could influence the correlations positively, but we consider this heterogeneity to replicate the population surgeons meet in their everyday practise. In retrospect we would consider including surgeon evaluation of nasal passage for comparison.

# Conclusion

This is the first paper to report correlations between minimal unilateral PNIF and the patient reported outcome measures NO-VAS, SNOT-4, SNOT-Rhino and SNOT-22 in a heterogenous cohort of patients with nasal pathology. NO-VAS shows stronger correlation with PNIF values than SNOT-4, SNOT-Rhino and SNOT-22. Multivariate regression analyses prove MinPNIF to be comparable to bilateral PNIF as a predictor of subjective nasal obstruction as measured by NO-VAS. Our results show MinPNIF have the added advantage of comparable ranges for symptomatic female and male patients.

Our analyses give reason to advocate the use of MinPNIF as a supplement when evaluating patients with nasal obstruction, but weak correlations impede its use as a stand-alone preoperative diagnostic test. Topical decongestion does not seem to provide added value evaluating patient symptom burden, and could possibly be excluded from routine PNIF measurements. The value of MinPNIF and other objective diagnostic parameters in preoperative diagnosis and postoperative outcome evaluation need further scientific attention.

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## Author contribution

All authors had full access to all the data in the study and take responsibility for the authenticity of the data and accuracy of the analyses. IV: Data collection, analysis and statistical work. Wrote the manuscript. TO: Co-wrote the manuscript. EAS, GBH: Data collection. Supervised the manuscript. FAD: Supervised the statistics, supervised the manuscript. IS: Supervised the manuscript.

### **Conflict of interest**

The authors report no conflicts of interest.

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